Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Comparative evaluation of effect of General anesthesia, Spinal anesthesia and Paracervical block on pain, nausea, vomiting and analgesic requirements in diagnostic Hysteroscopy.

Protocol summary

Study aim

Comparison of effect of General anesthesia, Spinal anesthesia and Paracervical block on pain, nausea, vomiting and analgesic requirements in diagnostic Hysteroscopy.

Design

This phase 2 clinical trial with parallel groups and without control group will be performed on 66 patients aged 18 to 45 years who are candidates for diagnostic hysteroscopy.

Settings and conduct

In general anesthesia group, 0.02mg/kg midazolam,1ug/kg Fentanyl and 2mg/kg of propofol are injected intravenously and the suitable LMA is placed.In spinal anesthesia group, after spinal anesthesia, 0.02 mg/kg of midazolam and 1ug/kg fentanyl are ingected intravenously for sedation. In paracervical group, first 0.02mg/kg midazolam and 1ug/kg fentanyl Injected intravenously and after 3-5 minutes,10 ml lidocaine 2% will inject by a spinal needle no.25 at 3, 9, 5 and 7 hours in cervico vaginal junction.The patient is then subjected to hysteroscopy with a rigid hysteroscope and vital signs, nausea, analgesic consumption and patient satisfaction at different times are measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients 18 to 45 years; ASA class1&2; Candidate for hysteroscopic surgery; Do not use analgesics for 24 hours before surgery; Absence of contraindications to spinal anesthesia and general anesthesia. Exclusion criteria: History of allergies to local anesthetics and propofol; Electrolyte disturbances; History of previous hysteroscopic surgery; History of nausea and vomiting following previous anesthesia or history of motion sickness; Lack of patient cooperation after initial interventions and coagulation disorders.

Intervention groups

In this study, patients in three groups of general anesthesia, spinal anesthesia and paracervical block are evaluated for vital signs, nausea, analgesic consumption and satisfaction.

Main outcome variables

The VAS of pain and analgesic requirment in recovery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120915010841N26**
Registration date: **2021-11-07, 1400/08/16**
Registration timing: **prospective**

Last update: **2021-11-07, 1400/08/16**
Update count: **0**

Registration date

2021-11-07, 1400/08/16

Registrant information

Name
Nahid Manuchehrian

Name of organization / entity
Hamedan University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-05, 1400/09/14

Expected recruitment end date

2022-03-05, 1400/12/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of effect of General anesthesia, Spinal anesthesia and Paracervical block on pain, nausea, vomiting and analgesic requirements in diagnostic Hysteroscopy.

Public title

Comparison of three anesthesia methods in hysteroscopic surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients 18 to 45 years ASA class1&2 Candidate for diagnostic hysteroscopic surgery Satisfaction to participate in the study Do not use analgesics for 24 hours before surgery Absence of contraindications to spinal anesthesia and general anesthesia

Exclusion criteria:

History of allergies to local anesthetics and propofol Cardiac,respiratory,renal and liver diseases Candidate patients for myomectomy or polypectomy with resectoscope Electrolyte disturbances (sodium, potassium and calcium Uterine prolapse History of previous cervical or hysteroscopic surgery History of nausea and vomiting following previous anesthesia or history of motion sickness Lack of patient cooperation after initial interventions Coagulation disorders

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan University of Medical Sciences

Street address

Mahdieh Street

City

Hamadan

Province

Hamadan

Postal code

6517838678

Approval date

2021-01-16, 1399/10/27

Ethics committee reference number

IR.UMSHA.REC.1399.875

Health conditions studied

1

Description of health condition studied

Hysteroscopic surgery under general anesthesia, spinal anesthesia or para cervical block

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Post operative pain

Timepoint

After surgery in recovery

Method of measurement

Using visual analog scale (VAS)

2

Description

Analgesic requirement

Timepoint

After surgery in recovery

Method of measurement

Based on the amount of analgesia requested by the patient

Secondary outcomes

1

Description

Systolic and Diastolic Blood Pressure

Timepoint

Before and after general or regional anesthesia, insertion of Spacolom and Tenacolom, dilation of cervix,insertion

of hysteroscope, biopsy and extraction of hysteroscope

Method of measurement

Non-invasive automatic barometric device

2

Description

Nausea & vomiting

Timepoint

After surgery in recovery

Method of measurement

Observation

3

Description

Heart Rate

Timepoint

Before and after general or regional anesthesia, insertion of Spacolom and Tenacolom, dilation of cervix,insertion of hysteroscope, biopsy and extraction of hysteroscope

Method of measurement

Pulseoximetry

4

Description

Shivering

Timepoint

After surgery in recovery

Method of measurement

Observation

5

Description

Satisfaction rate

Timepoint

Before discharge from recovery

Method of measurement

Asking the patient

Intervention groups

1

Description

Intervention group1: In all patients after entering the operating room, using a 18 intravenous lines, after receiving 5 ml/kg of serum Ringer, in general anesthesia group, 0.02mg/kg midazolam, 1ug /kg Fentanyl and 2mg/kg of propofol are injected intravenously and then the suitable LMA is placed (proportional to the patient's weight) and is used to maintain anesthesia from 1.2% isoflurane and 50%N2o.The patient is then subjected to hysteroscopy with a rigid hysteroscope (Storz Hysteroscope No. 7, Germany), and the uterine cavity is dilated using Glycine solution1.5% and vital signs(Saadat,162 model, non invasive monitoring, Iran), nausea, pain (VAS), analgesic consumption and patient satisfaction(%) at different times are measured.

Category

Treatment - Drugs

2

Description

Intervention group 2: In all patients after entering the operating room, using a 18 intravenous lines, after receiving serum 5 ml/kg of serum Ringer, in spinal anesthesia group, the patient is placed in a sitting position and after determining the subarachnoid space in the L3-L4 or L4-L5 space, 2.5 mg of 0.5% bupivacaine is injected.Then, sensory level is examined by pinprick and in an anesthetic level of T10, the surgical procedure started and 0.02 mg/kg of midazolam and 1ug/kg fentanyl are used for sedation.The patient is then subjected to hysteroscopy with a rigid hysteroscope (Storz Hysteroscope No. 7, Germany), and the uterine cavity is dilated using Glycine solution1.5% and vital signs(Saadat,162 model, non invasive monitoring, Iran), nausea, pain (VAS), analgesic consumption and patient satisfaction(%) at different times are measured.

Category

Treatment - Drugs

3

Description

Intervention group 3: In all patients after entering the operating room, using a 18 intravenous lines, after receiving 5 ml/kg of serum Ringer, in paracervical group, first 0.02mg/kg midazolam and 1ug/kg fentanyl Injected intravenously and after 3-5 minutes, 10 ml lidocaine 2% will inject by a spinal needle no.25 at 3, 9, 5 and 7 hours in cervico vaginal junction, and after 5 minutes, the patient is evaluated for adequate anesthesia and surgery will begin. The patient is then subjected to hysteroscopy with a rigid hysteroscope (Storz Hysteroscope No. 7, Germany), and the uterine cavity is dilated using Glycine solution1.5% and vital signs(Saadat,162 model, non invasive monitoring, Iran), nausea, pain (VAS), analgesic consumption and patient satisfaction(%) at different times are measured.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Hamedan University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
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Position
Associate professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available